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Draft Proposed FDA Rule August 7, 1995

Applies to cigarettes and smokeless tobacco products, not cigars or pipe tobacco.

Prohibit sales to individuals under 18 years old (federalizing state law). Youth-oriented access restrictions designed to limit sales to face-to-face transactions, e.g., require retailers to verify age with a photo i.d. card and prohibit: vending machines, mail order purchases, self-service displays, coupons sent through the mail, free samples, and sale

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of "loosies" (single cigarettes) and /kiddie packs" (fewer than 20 cigarettes per pack).)

6) (line of seelt Manufacturers are obliged to inspect (whenever they routinely visit a relatifistic) to ensure proper labeling, advertising and distribution of their products. When they see something that violates the rule. such as a self sorvice diaplay, they must remove it

Prohibit manufacturers from using the trade name of a non-tobacco product for a cigarette of order smokeless tobacco product, e.g., Harley Davidson, Cartier and Ritz cigarettes. These latter three names, along with any other brands already named after a non-tobacco product, will be exempted (grandfathered) from the rule. exempted (grandfathered) from the rule.

Permit sponsorship of events in corporate name only, e.g., the Phillip Morris, rather than the Virginia Slims, Tennis Tournament. This provision does not include teams or entries in events, e.g., stockcars and their crews, which are treated as "reminder advertising." Any corporate names used for these purposes must have been in existence as of January 1, 1995.

Ban outdoor advertising within 1000 feet of schools and playgrounds. This includes outdoor but not indoor signs at buildings within 1000 feet of schools. Gurlen on intustate

For all outdoor advertising that is more than 1000 feet from schools or playgrounds hims The (including the inside and outside of buses, billboards at sports facilities, stockcars and their crews), permit only black and white, text-only (tombstone) ads: The same approach for all youth realleship of "point of sale" ads (e.g., clocks and exit signs in retail stores).

Mo render adjustered en publications with south readership of 15% or more than 2 million, whichever is less, but no restrictions would be imposed on print advertising below that threshold (other than the warning labels described in #10 below). Alldirect mail ads to the home would be tombstone style. veach

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All cigarette advertising (but not smokeless tobacco advertising) that is not on a package label, e.g., billboards, print ads, and direct mail, but not reminder ads such as those on stockcars and crews and other similar event participants, must include a statement that the product is a cigarette, that it is "a nicotine delivery device," and an additional warning. The label must be readable, clear, conspicuous and prominently displayed and must be contiguous with the Surgeon General's warning. The FDA is soliciting comments on how

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best to meet these standards. An example of an appropriate warning is: "About one of three children who become smokers will die from their smoking."

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Ban sale or giveaways of caps, shirts, gymbags and other "trinkets" which carry a tobacco brand name or other tobacco product identification. Ban lotteries or contests where the "entry fee" is a cigarette purchase. Ban the distribution of non-tobacco items in exchange for proof of purchase of tobacco products; this provision of the rule eliminates the "Camel Cash" and "Marlboro Miles" programs in which gifts are purchased using credits gained by buying tobacco products. Lowly we have surely " - but don't pay

Create a million per year industry-funded educational program. Each company would pay the portion of \$150 million each year equal to its share of the total advertising and promotional expenditures of the industry.

The \$150 million is based on historical experience. From 1967 to 1971 the FTC required the industry to fund an anti-smoking television ad campaign. The campaign cost about \$75 million per year in 1970 dollars -- which is approximately \$300 million in current dollars. The rule thus requires the new ad campaign to be approximately half the real cost of the 1967-71 campaign.

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Provide that if within five years, youth smoking has not been reduced to 50% of its 1993 and level, additional measures would be taken. The FDA will receive comments on what measures could be taken if youth smoking were not reduced by 50% within 5 years.

- More restrictive state laws are not preempted by this rule. States and localities may request an advisory opinion from the FDA as to whether state or local requirements are preempted.
- NO 15 General reporting such as sending copies of ads and labels to the FDA is required.

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NO 16 As with other drug delivery devices, advertising cannot be false or misleading.

Cost Analysis (appendix to rule)

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To comply with the rule, FDA estimates the manufacturers and retailers will incur one time costs ranging from approximately \$26 to \$39 million plus annual operating costs of approximately \$22x million, which includes the \$150 million educational campaign outlined in #12 above.

The rule acknowledges that there will be short term impacts on tobacco advertisers, suppliers of promotional products and vending operators, although those figures are not included in the figures outlined above. While it is difficult to estimate the loss to advertisers,

Camel in the past has held letteries for vacations, recreational vehicles, etc.

the economic estimates in the rule imply that if the tobacco industry were to cut its advertising outlays by one half in the "text only" fora, it would be an approximate loss of less than one half of one percent of the \$131.3 billion spent on U.S. media advertising for all products, tobacco and non-tobacco. Vending machine operators will lose approximately 3.4% of their annual business, according to the economic estimates.

The rule also points out that each small business that does not check for i.d. now will incur a cost of approximately \$320 the first year; those that already check i.d. will incur approximately a \$35 cost the first year. In addition, it estimates the loss in industry revenue to reduced cigarette consumption to be approximately \$143 million in the first year, rising to approximately \$1.2 billion in the tenth year. It estimates this as a loss of approximately 1000 jobs per year for ten years.

This rule will also reduce state tobacco tax revenues by approximately \$31 million in the first year rising to \$252 million in the tenth year. (The preamble points out that states can make up the lost revenue by increasing their tax rates.)

Due to the prevention of premature deaths due to tobacco, health benefits for the population are estimated to be approximately \$28 to \$43 billion per year if youth smoking is reduced by 50%.